DOCKET NO.: MPCI-0031 Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

## Listing of Claims:

Please amend claims 12, 22, 28, 29, 31 and cancel claims 1-11 and 34-36 as follows:

Claims 1- 11 are cancelled.

12. (Currently Amended) A drug dosage form prepared by compression techniques comprising:

a substantially non-volatile, pharmaceutically acceptable oil, and
a compound susceptible to moisture-induced degradation admixed with
a substantially non-volatile, pharmaceutically acceptable oil, treated with the
substantially non-volatile, pharmaceutically acceptable oil to substantially waterproof the
compound susceptible to moisture-induced degradation;
the drug dosage form prepared by:

- (a) dispersing the compound susceptible to moisture-induced degradation in the substantially non-volatile, pharmaceutically acceptable oil; and
- (b) compacting the compound susceptible to moisture-induced degradation into dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.
- 13. (Original) The drug dosage form of claim 12 wherein the oil is an animal or vegetable oil.
- 14. (Original) The drug dosage form of claim 12 wherein said oil is olive, corn, peanut, nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.
- 15. (Original) The drug dosage form of claim 12 wherein the oil is a mineral oil or silicone oil.

DOCKET NO.: MPCI-0031
Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

- 16. (Original) The drug dosage form of claim 12 wherein the compound oil admixture is present within a capsule.
- 17. (Original) The drug dosage form of claim 12 wherein the compound oil admixture is present within a soft shell capsule.
- 18. (Original) The drug dosage form of claim 12 wherein the compound oil admixture is present within a specially sealed hard-shell capsule.
- 19. (Original) The drug dosage form of claim 12 wherein at least some of the compound oil admixture is adsorbed on a pharmaceutically acceptable excipient.
- 20. (Original) The drug dosage form of claim 12 wherein the excipient having the compound oil admixture adsorbed thereupon is within a capsule.
- 21. (Original) The drug dosage form of claim 12 wherein the excipient having the compound oil admixture adsorbed thereupon is within a tablet.
- 22. (Currently Amended) A drug dosage form prepared by compression techniques comprising:
- a pharmaceutically acceptable excipient admixed with a substantially non-volatile pharmaceutically acceptable oil; and
  - a compound susceptible to moisture-induced degradation, and
- a pharmaceutically acceptable excipient admixed with a substantially non-volatile; pharmaceutically acceptable oil, treated with the pharmaceutically acceptable excipient to substantially waterproof the compound susceptible to moisture-induced degradation: wherein the drug dosage form is prepared by:
- (a) dispersing the compound susceptible to moisture-induced degradation in the pharmaceutically acceptable excipient:

DOCKET NO.: MPC1-0031 Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

- (b). compacting the compound susceptible to moisture-induced degradation into dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.
- 23. (Original) The drug dosage form of claim 22 wherein the oil is an animal or vegetable oil.
- 24. (Original) The drug dosage form of claim 22 wherein said oil is olive, corn, peanut, nut, soy, rapeseed, cononseed, vitamin E, fish, or tallow-derived oil.
- 25. (Original) The drug dosage form of claim 22 wherein the oil is a mineral oil or silicone oil.
- 26. (Original) The drug dosage form of claim 22 wherein the drug and the excipient oil admixture are present within a capsule.
- 27. (Original) The drug dosage form of claim 22 wherein the drug and the excipient oil admixture are present within a tablet.
- 28. (Currently Amended) A drug form prepared by compression techniques comprising:

  a compound susceptible to moisture-induced degradation admixed treated with

  a first pharmaceutically acceptable oil together with to substantially waterproof the

  compound susceptible to moisture-induced degradation; and
- a pharmaceutically acceptable excipient admixed with a second pharmaceutically acceptable oil to substantially waterproof the pharmaceutically acceptable excipient, wherein the first pharmaceutical acceptable oil is different from the second pharmaceutically acceptable oil;

wherein the drug dosage form [[is]] prepared by:

(a) dispersing the compound susceptible to moisture-induced degradation in the pharmaceutically acceptable excipient;

<

DOCKET NO.: MPCI-0031 Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR \$ 1.116

- (b). compacting the compound susceptible to moisture-induced degradation into dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.
- 29. (Currently Amended) The drug dosage form of claim 28 wherein the first pharmaceutically acceptable oil is an animal oil and the second pharmaceutically acceptable oils are, independently, an animal or oil is a vegetable oil.
- 30. (Original) The drug dosage form of claim 28 wherein the first and the second pharmaceutically acceptable oils are, independently, olive, com, peanut, nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.
- 31. (Currently Amended) The drug dosage form of claim 28 wherein the first pharmaceutically acceptable oil is an mineral oil and the second pharmaceutically acceptable oils are, independently, a mineral or oil is a silicone oil.
- 32. (Original) The drug dosage form of claim 28 wherein the compound oil admixture and the excipient oil admixture are present within a capsule.
- 33. (Original) The drug dosage form of claim 28 wherein the compound oil admixture and the excipient oil admixture are present within a tablet.

Claims 34-36 are cancelled.

37. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound which has not been processed employing high compression.

DOCKET NO.: MPCI-0031 Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

- 38. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound admixed with a substantially non-volatile, pharmaceutically acceptable oil.
- 39. (Withdrawn) The method of claim 38 wherein the compound oil admixture is present within a capsule.
- 40. (Withdrawn) The method of claim 38 wherein the compound oil admixture is adsorbed on a pharmaceutically acceptable excipient.
- 41. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and a pharmaceutically acceptable excipient admixed with a substantially non-volatile, pharmaceutically acceptable oil.
- 42. (Withdrawa) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and at least one pharmaceutically acceptable hydrophobic powder.